

**IN THE UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE**

PAR PHARMACEUTICAL, INC., PAR
STERILE PRODUCTS, LLC, and ENDO PAR
INNOVATION COMPANY, LLC

Plaintiffs,

v.

AMERICAN REGENT, INC.

Defendant.

C.A. No. 19-cv-1490-CFC

PLAINTIFFS' ANSWER TO DEFENDANT'S COUNTERCLAIMS

Plaintiffs Par Pharmaceutical, Inc., Par Sterile Products, LLC, and Endo Par Innovation Company, LLC (collectively “Par”), hereby set forth their Answer to the Counterclaims of Defendant American Regent, Inc. (“American Regent”) as follows:

NATURE OF THE ACTION

1. Paragraph 1 contains legal conclusions to which no response is required. To the extent a response is required. Par admits that American Regent seeks a declaratory judgment. Except as expressly admitted, Par denies the remaining allegations of Paragraph 1 as stated.

PARTIES

2. Par admits the allegations of Paragraph 2 upon information and belief.
3. Par admits the allegations of Paragraph 3.
4. Par admits the allegations of Paragraph 4.
5. Par admits the allegations of Paragraph 5.
6. Par admits the allegations of Paragraph 6.

JURISDICTION & VENUE

7. Paragraph 7 states legal conclusions to which no answer is required. To the extent an answer is required, Par admits that American Regent seeks declaratory judgment under 28 U.S.C. §§ 2201 and 2202 and the Patent Laws of the United States. Except as expressly admitted, Par denies the remaining allegations of Paragraph 7 as stated.

8. Paragraph 8 states legal conclusions to which no answer is required. To the extent an answer is required, Par does not contest that this Court has subject matter jurisdiction over American Regent's Counterclaims with respect to the '526, '209, '478 and '785 patents. Par denies the remaining allegations of this paragraph and denies that American Regent states or has any valid counterclaims.

9. Paragraph 9 states legal conclusions to which no answer is required. To the extent an answer is required, Par does not contest personal jurisdiction in this judicial district for the limited purpose of this action only. Par denies the remaining allegations of Paragraph 9.

10. Par denies that American Regent has a right to engage in the making, using, offering for sale, and selling of the products described in NDA No. 212593 without license from Par. Par denies the remaining allegations of Paragraph 10.

11. Paragraph 11 states legal conclusions to which no answer is required. To the extent an answer is required, Par does not contest that venue in this District with respect to American Regent's Counterclaims is proper.

BACKGROUND

12. Par admits the allegations of Paragraph 12.

13. Par admits the allegations of Paragraph 13.

14. Par admits the allegations of Paragraph 14.

15. Par admits the allegations of Paragraph 15.

16. Par admits that the PTO duly and legally issued U.S. Patent No. 9,744,239 (the “’239 Patent”), entitled “Vasopressin Formulations for Use in Treatment of Hypotension,” on August 29, 2017. Par further admits that Exhibit A purports to be a copy of the ’239 Patent.

17. Par admits the allegations of Paragraph 17.

18. Paragraph 18 contains legal conclusions to which no response is required.

19. Paragraph 19 contains legal conclusions to which no response is required.

20. Par admits that, on or about June 27, 2019, American Regent sent notice of submission of a Paragraph IV certification to Par Pharmaceutical, Inc. and Par Sterile Products, LLC. Par denies the remaining allegations of Paragraph 20.

21. Par admits that, on or about June 28, Par Pharmaceutical, Inc. and Par Sterile Products, LLC received a copy of the Paragraph IV Notice. Par denies the remaining allegations of Paragraph 21.

22. Par admits the allegations of Paragraph 22.

23. Par admits the allegations of Paragraph 23.

24. Par admits that the ’239 Patent is listed in the Orange Book with respect to VASOSTRICT®. Par further admits that the original Complaint filed in this action (D.I. 1) does not allege infringement of the ’239 Patent. Par denies the remaining allegations of Paragraph 24.

25. Paragraph 25 contains legal conclusions to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 25.

FIRST COUNTERCLAIM
DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE ’785 PATENT

26. Par incorporates by reference its responses to each of the preceding paragraphs of American Regent’s Counterclaims. Except as expressly admitted above, Par denies any

remaining allegations of the preceding paragraphs of American Regent's Counterclaims as if fully set forth herein.

27. Par denies the allegations of Paragraph 27.

28. Par admits that the quoted language appears in Claim 2 of the '785 Patent. Par denies the remaining allegations of Paragraph 28.

29. Par denies the allegations of Paragraph 29.

30. Par denies the allegations of Paragraph 30.

31. Par denies the allegations of Paragraph 31.

SECOND COUNTERCLAIM
DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '209 PATENT

32. Par incorporates by reference its responses to each of the preceding paragraphs of American Regent's Counterclaims. Except as expressly admitted above, Par denies any remaining allegations of the preceding paragraphs of American Regent's Counterclaims as if fully set forth herein.

33. Par denies the allegations of Paragraph 33.

34. Par admits that the quoted language appears in Claim 11 of the '209 Patent. Par denies the remaining allegations of Paragraph 34.

35. Par denies the allegations of Paragraph 35.

36. Par denies the allegations of Paragraph 36.

37. Par denies the allegations of Paragraph 37.

THIRD COUNTERCLAIM
DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '478 PATENT

38. Par incorporates by reference its responses to each of the preceding paragraphs of American Regent's Counterclaims. Except as expressly admitted above, Par denies any

remaining allegations of the preceding paragraphs of American Regent's Counterclaims as if fully set forth herein.

39. Par denies the allegations of Paragraph 39.

40. Par admits that the language "10 mM acetate buffer" appears in claim 1 of the '478 Patent. The remainder of Paragraph 40 contains legal conclusions to which no response is required.

41. Par denies the allegations of Paragraph 41.

42. Par denies the allegations of Paragraph 42.

43. Par denies the allegations of Paragraph 43.

FOURTH COUNTERCLAIM
DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '526 PATENT

44. Par incorporates by reference its responses to each of the preceding paragraphs of American Regent's Counterclaims. Except as expressly admitted above, Par denies any remaining allegations of the preceding paragraphs of American Regent's Counterclaims as if fully set forth herein.

45. Par denies the allegations of Paragraph 45.

46. Par denies the allegations of Paragraph 46.

47. Par denies the allegations of Paragraph 47.

FIFTH COUNTERCLAIM
DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '239 PATENT

48. Par incorporates by reference its responses to each of the preceding paragraphs of American Regent's Counterclaims. Except as expressly admitted above, Par denies any remaining allegations of the preceding paragraphs of American Regent's Counterclaims as if fully set forth herein.

49. American Regent's NDA No. 212593 is the subject of further investigation and discovery, such that Par is without sufficient information to admit or deny the allegations of Paragraph 49.

50. American Regent's NDA No. 212593 is the subject of further investigation and discovery, such that Par is without sufficient information to admit or deny the allegations of Paragraph 50.

51. Par admits that Exhibit B purports to be a Response to Non-Final Office Action from the Prosecution History of the '239 Patent, and state that that document speaks for itself. The remainder of Paragraph 51 contains legal conclusions to which no response is required.

52. Paragraph 52 contains legal conclusions to which no response is required.

53. American Regent's NDA No. 212593 is the subject of further investigation and discovery, such that Par is without sufficient information to admit or deny the allegations of Paragraph 53.

54. American Regent's NDA No. 212593 is the subject of further investigation and discovery, such that Par is without sufficient information to admit or deny the allegations of Paragraph 54.

55. American Regent's NDA No. 212593 is the subject of further investigation and discovery, such that Par is without sufficient information to admit or deny the allegations of Paragraph 55.

56. Par denies the allegations of Paragraph 56.

SIXTH COUNTERCLAIM
DECLARATORY JUDGMENT OF INVALIDITY OF THE '478 PATENT

57. Par incorporates by reference its responses to each of the preceding paragraphs of American Regent's Counterclaims. Except as expressly admitted above, Par denies any

remaining allegations of the preceding paragraphs of American Regent's Counterclaims as if fully set forth herein.

58. Par denies the allegations of Paragraph 58.

59. Par denies the allegations of Paragraph 59.

60. Par denies the allegations of Paragraph 60.

61. Par denies the allegations of Paragraph 61.

62. Par denies the allegations of Paragraph 62.

SEVENTH COUNTERCLAIM
DECLARATORY JUDGMENT OF INVALIDITY OF THE '526 PATENT

63. Par incorporates by reference its responses to each of the preceding paragraphs of American Regent's Counterclaims. Except as expressly admitted above, Par denies any remaining allegations of the preceding paragraphs of American Regent's Counterclaims as if fully set forth herein.

64. Par denies the allegations of Paragraph 64.

65. Par denies the allegations of Paragraph 65.

66. Par denies the allegations of Paragraph 66.

67. Par denies the allegations of Paragraph 67.

68. Par denies the allegations of Paragraph 68.

EIGHTH COUNTERCLAIM
DECLARATORY JUDGMENT OF INVALIDITY OF THE '209 PATENT

69. Par incorporates by reference its responses to each of the preceding paragraphs of American Regent's Counterclaims. Except as expressly admitted above, Par denies any remaining allegations of the preceding paragraphs of American Regent's Counterclaims as if fully set forth herein.

70. Par denies the allegations of Paragraph 70.

71. Par denies the allegations of Paragraph 71.

72. Par denies the allegations of Paragraph 72.

73. Par denies the allegations of Paragraph 73

74. Par denies the allegations of Paragraph 74.

NINTH COUNTERCLAIM
DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '785 PATENT

75. Par incorporates by reference its responses to each of the preceding paragraphs of American Regent's Counterclaims. Except as expressly admitted above, Par denies any remaining allegations of the preceding paragraphs of American Regent's Counterclaims as if fully set forth herein.

76. Par denies the allegations of Paragraph 76.

77. Par denies the allegations of Paragraph 77.

78. Par denies the allegations of Paragraph 78.

79. Par denies the allegations of Paragraph 79.

80. Par denies the allegations of Paragraph 80.

TENTH COUNTERCLAIM
DECLARATORY JUDGMENT OF UNENFORCEABILITY OF THE '478 PATENT,
THE '526 PATENT, THE '209 PATENT, THE '239 PATENT, AND THE '785 PATENT
BASED ON INEQUITABLE CONDUCT AND UNCLEAR HANDS

81. Par incorporates by reference its responses to each of the preceding paragraphs of American Regent's Counterclaims. Except as expressly admitted above, Par denies any remaining allegations of the preceding paragraphs of American Regent's Counterclaims as if fully set forth herein.

82. Par denies the allegations of Paragraph 82.

83. Par admits that plaintiff Par Sterile Products was aware of the pH of Pitressin and that Par Sterile Products filed an NDA that included a comparison of the original formulation of Vasostriect with Pitressin. Par denies the remaining allegations of Paragraph 83.

84. Paragraph 84 contains legal conclusions to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 84.

85. The cited declarations speak for themselves. Par denies any characterization of the cited declarations and the remaining allegations of Paragraph 85 as stated.

86. Paragraph 86 contains legal conclusions to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 86.

87. Par denies the allegations of the first sentence of Paragraph 87. The cited office action rejections speak for themselves. Par denies any characterization of the cited rejections and the remaining allegations of Paragraph 87 as stated.

88. Par admits that a Non-Final Rejection of U.S. Appl. No. 16/044056, dated September 18, 2018 states “the Biopharmaceutics Review establishes that the formulation publically available prior to September 26, 2012 contains 20 U/mL vasopressin, chlorobutanol, acetic acid, and water, and has a pH of about 3.6...”

89. Par denies the allegations of Paragraph 89.

90. Par denies the allegations of Paragraph 90.

91. Par denies the allegations of Paragraph 91.

92. Par denies the allegations of Paragraph 92.

93. Par denies the allegations of Paragraph 93.

94. Par denies the allegations of Paragraph 94.

AFFIRMATIVE DEFENSES

First Affirmative Defense

Defendant's Counterclaims fail to state a claim upon which relief can be granted.

PRAYER FOR RELIEF

Par denies all remaining allegations not expressly admitted or responded to herein. Par further denies that American Regent is entitled to the relief requested, or to any relief whatsoever. Par pray for relief as follows:

- A. Entry of judgment in favor of Par and against American Regent with respect to Defendant's Counterclaims, and an award of the relief sought in Par's Complaint;
- B. Dismissal of American Regent's Counterclaims with prejudice;
- C. An award to Par of its attorney's fees, costs, and expenses; and
- D. Such other relief as the Court deems equitable and just.

Dated: September 17, 2019

Respectfully submitted,

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